This document is scheduled to be published in the
Federal Register on 12/11/2023 and available online at
https://federalregister.gov/d/2023-27112, and on **https://govinfo.gov**

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Brian Bailey, PhD; 240-669-5128 or 301-201-9217; bbailey@mail.nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852: tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Enhanced Immune Response with Stabilized Norovirus VLPs: A Next-Generation Vaccine Approach.

Description of Technology:

This technology includes a novel advancement in developing vaccines targeting norovirus, tailored specifically for a more robust and effective response. It centers around an improved version of Virus-Like Particles (VLPs) uniquely engineered for greater stability and efficacy. These enhanced VLPs are designed to remain intact even when faced with the body's immune responses, overcoming a key limitation of previous vaccine designs. This stability is crucial in ensuring the vaccine's effectiveness, particularly in individuals with more robust immune systems who have shown limited response to traditional vaccines. Additionally, the modified VLPs are likely more resistant to degradation, making them a more reliable and durable solution in vaccination campaigns. This innovation could be a significant step in offering a more effective vaccine option for widespread use.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Enhanced Norovirus Vaccination: Specially designed to improve the effectiveness of vaccines against norovirus, particularly in individuals with previously low response rates to traditional vaccines.
- Broad-Scale Immunization Programs: Suitable for large-scale public health initiatives due to its increased stability and durability, potentially reducing the frequency of booster shots.

- Platform for Future Vaccine Development: The stabilization techniques used in this technology could be applied to other vaccine formulations, paving the way for more robust and effective vaccines against various pathogens.

Competitive Advantages:

- Provides enhanced stability and efficacy in norovirus VLP vaccines, ensuring effectiveness even in individuals with strong immune responses who have previously shown limited vaccine response.
- Its innovative design increases the VLPs' resistance to degradation, offering a more durable and reliable option for large-scale immunization programs.

Development Stage:

- Pre-Clinical

Inventors: Lisa Lindesmith, Ralph Baric, George Georgiou, Peter Kwong, Raffaello Veradi, Yaroslav Tsybovsky, Jason Gorman, Gwo-Yu Chuang and Li Ou, all of NIAID.

Publications: Lu, Yuan et al. "Assessing sequence plasticity of a virus-like nanoparticle by evolution toward a versatile scaffold for vaccines and drug delivery." *Proceedings of the National Academy of Sciences of the United States of America* vol. 112,40 (2015): 12360-5. DOI: 10.1073/pnas.1510533112 at https://doi.org/10.1073/pnas.1510533112; Porta, Claudine et al. "Rational engineering of recombinant picornavirus capsids to produce safe, protective vaccine antigen." *PLoS pathogens* vol. 9,3 (2013): e1003255. DOI: 10.1371/journal.ppat.1003255 at https://doi.org/10.1371/journal.ppat.1003255; Mateo, Roberto et al. "Engineering viable foot-and-mouth disease viruses with increased

thermostability as a step in the development of improved vaccines." *Journal of virology* vol. 82,24 (2008): 12232-40. DOI: 10.1128/JVI.01553-08 at https://doi.org/10.1128/jvi.01553-08; Bertolotti-Ciarlet, Andrea et al. "Structural requirements for the assembly of Norwalk virus-like particles." *Journal of virology* vol. 76,8 (2002): 4044-55. DOI: 10.1128/jvi.76.8.4044-4055.2002 at https://doi.org/10.1128/jvi.76.8.4044-4055.2002; Prasad, B V et al. "X-ray crystallographic structure of the Norwalk virus capsid." *Science (New York, N.Y.)* vol. 286,5438 (1999): 287-90. DOI: 10.1126/science.286.5438.287 at https://doi.org/10.1126/science.286.5438.287.

Intellectual Property: HHS Reference No. E-178-2019-0; U.S. Provisional Patent Application No. 63/091,824, filed on October 14, 2020; PCT Patent Application No. PCT/US2021/55018, filed October 14, 2021; U.S. National Stage patent application, U.S. 18/031,602, filed April 12, 2023.

Licensing Contact: To license this technology, please contact Brian Bailey, PhD; 240-669-5128 or 301-201-9217; bbailey@mail.nih.gov, and reference E-178-2019.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Brian Bailey, PhD; 240-669-5128 or 301-201-9217; bbailey@mail.nih.gov.

Dated: December 5, 2023.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2023-27112 Filed: 12/8/2023 8:45 am; Publication Date: 12/11/2023]